

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ )	
FENFLURAMINE/DEXFENFLURAMINE )	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION )	
)	
THIS DOCUMENT RELATES TO: )	
)	
SHEILA BROWN, et al. )	CIVIL ACTION NO. 99-20593
v. )	
)	
AMERICAN HOME PRODUCTS )	2:16 MD 1203
CORPORATION )	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

852|

Bartle, C.J.

August 31, 2010

Sadie R. Tafoya ("Ms. Tafoya" or "claimant") a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, David R. Clarke, M.D. Dr. Clarke is no stranger to this litigation. According to the Trust, he has signed in excess of 113 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated July 8, 2002, Dr. Clarke attested in Part II of Ms. Tafoya's Green Form that she suffered from moderate mitral regurgitation and an abnormal left atrial

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2. (...continued)

serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

dimension.<sup>3</sup> Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$501,985.<sup>4</sup>

In the report of claimant's echocardiogram, Dr. Clarke stated that claimant had left atrial enlargement, which he measured as 5.31 cm in the supero-inferior systolic dimension. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See Settlement Agreement § IV.B.2.c.(2)(b)ii).

In January, 2004, the Trust forwarded the claim for review by George A. Davis, M.D., one of its auditing cardiologists. In audit, Dr. Davis concluded that there was no reasonable medical basis for Dr. Clark's finding that Ms. Tafoya had an abnormal left atrial dimension because claimant's left atrial dimension measured 5.0 cm in the apical four-chamber view and 3.4 cm in the parasternal long-axis view. Dr. Davis

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3. Dr. Clarke also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of moderate mitral regurgitation, the only issue is whether claimant had an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim.

explained that "[t]he [left atrium] was measured diagonally in the parasternal view, and also by M Mode. The [supero-inferior] dimension included a measurement to the valve leaflets, instead of the valve annulus." Dr. Davis also determined that claimant had a reduced ejection fraction in the range of 50% to 60%, but noted that claimant's "LV function was normal" and that there was a reasonable medical basis for the attesting physician's Green Form representation that claimant did not have a reduced ejection fraction.<sup>5</sup>

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying Ms. Tafoya's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>6</sup> In contest, claimant submitted an affidavit from Dr. Clarke, who reaffirmed his finding that claimant's echocardiogram demonstrated an abnormal left atrial dimension. Claimant also submitted a still frame image that purportedly demonstrated a left atrial supero-inferior systolic

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5. An ejection fraction is considered reduced for purposes of a claim for Level II benefits based on damage to the mitral valve if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b)iv).

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Tafoya's claim.

dimension greater than 5.3 cm. In addition, claimant contended that while Dr. Davis identified certain errors in Dr. Clarke's measurements, he did not provide his own measurement of claimant's left atrial dimension.<sup>7</sup> Claimant also argued that the attesting physician's finding of a reduced ejection fraction in the range of 50% to 60% entitled her to Level II Matrix Benefits. According to claimant, "[t]here is a huge difference between 73% and 50%-60% and to categorize them as the same is unreasonable."

The Trust then issued a final post-audit determination, again denying Ms. Tafoya's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Tafoya's claim should be paid. On February 9, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4470 (Feb. 9, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 15, 2005. Under the Audit Rules, it is within the Special Master's discretion to

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7. To the contrary, Dr. Davis determined that claimant's left atrial supero-inferior dimension measured 5.0 cm and that claimant's left atrial antero-posterior dimension measured 3.4 cm.

appoint a Technical Advisor<sup>8</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had at least one complicating factor necessary to receive Level II Matrix Benefits. See Audit Rule 24. Ultimately, if we determine that there is no reasonable medical basis for this claim, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for this claim, we must enter an Order directing the Trust to pay the

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Tafoya makes the same arguments she made in contest; namely, that Dr. Davis failed to provide a measurement regarding the size of her left atrium and that she is entitled to Matrix Benefits based on the auditing cardiologist's finding that she had a reduced ejection fraction in the range of 50% to 60%.

In response, the Trust argues that, in his supplemental opinion, Dr. Clarke merely repeats his Green Form representation regarding claimant's left atrial dimension and does not address the auditing cardiologist's specific findings at audit. In addition, the Trust asserts that claimant cannot raise in show cause a new claim based on a reduced ejection fraction. Finally, the Trust submits that Dr. Davis properly determined that there was a reasonable medical basis for Dr. Clarke's representation that claimant's ejection fraction was greater than 60%.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension. Specifically, Dr. Abramson stated, in pertinent part, that:

I measured normal antero-posterior systolic dimensions of 3.5 cm, 3.6 cm, and 3.7 cm in the parasternal long axis view (Green Form states >4.0 cm is abnormal). I also measured normal supero-inferior dimensions of 5.0 cm, 5.1 cm, and 5.1 cm in the apical-4-chamber view (Green Form states >5.3 cm is abnormal).

The measurement on the tape in the parasternal long-axis is tangential to the long axis of the left atrium which will result in an erroneously large left atrial measurement. The measurement in the apical-4-chamber view is also incorrect because it extends from the mitral leaflets, not the mitral annulus as shown in the Green Form.

In addition, Dr. Abramson concluded that there was no reasonable medical basis to find that claimant's ejection fraction was in the range of 50% to 60%. Specifically, Abramson noted, in relevant part, that:

The ejection fraction in this patient is >60% and within normal limits. All walls are contracting normally. I measured three ejection fractions of 65%, 67% and 68% using the Simpson's method of discs.

In response to the Technical Advisor Report, claimant submits that the echocardiogram tape "has been with the Trust for over four and [a] half years and arguably has degraded over time." Claimant also argues that the Technical Advisor's opinion should be given no greater weight than any other expert's opinion.

After reviewing the entire Show Cause record, we find claimant's arguments are without merit. First, claimant does not contest the findings of the auditing cardiologist and the Technical Advisor that there is no reasonable medical basis for concluding that Ms. Tafoya had an abnormal left atrial dimension. Specifically, Dr. Davis determined that "[t]he [left atrium] was measured diagonally in the parasternal view, and also by M Mode. The [supero-inferior] dimension included a measurement to the

valve leaflets, instead of the valve annulus." Similarly, Dr. Abramson observed that "[t]he measurement on the tape in the parasternal long-axis is tangential to the long axis of the left atrium which will result in an erroneously large left atrial measurement" and that "[t]he measurement in the apical-4-chamber view is also incorrect because it extends from the mitral leaflets, not the mitral annulus as shown in the Green Form." On this basis alone, claimant has failed to meet her burden in proving that there is a reasonable medical basis for finding that she had an abnormal left atrial dimension.

We also disagree with claimant that she is entitled to Matrix Benefits based on a reduced ejection fraction. Although Ms. Tafoya relies on the auditing cardiologist's finding that claimant's ejection fraction was in the range of 50% to 60%, the auditing cardiologist also concluded that there was a reasonable medical basis for her attesting physician's representation that she did not have a reduced ejection fraction. Moreover, the Technical Advisor reviewed claimant's echocardiogram and determined that there is no reasonable medical basis for finding that claimant had an ejection fraction in the range of 50%-60%. As Dr. Abramson explained, "[t]he ejection fraction in this patient is >60% and within normal limits.... I measured three ejection fractions of 65%, 67% and 68% using the Simpson's method of discs."

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable

medical basis for finding that she had an abnormal left atrial dimension or a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Tafoya's claim for Matrix Benefits.